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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,492	03/04/2002	Timothy A.M. Chuter	BSI-584US	5068

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RATNER PRESTIA
P.O. BOX 980
VALLEY FORGE, PA 19482

EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
06/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/090,492	CHUTER ET AL.	
	Examiner	Art Unit	
	AMY T. LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11,12,15,29-46,48,49,56,62,70,87 and 88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 9, 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,652,580 in view of U.S. Patent No. 2,030,791. US '580 discloses a bifurcated graft component that is attached to an expandable frame (fixation device) through attaching structures (ties). The ties are further taught as longitudinally separating the graft from the expandable frame. Although US '580 does not specifically disclose the graft legs being attached, an anchoring structure, or radiopaque markers, such elements are well known in the art and would have been obvious at the time of the invention.

Additionally, Applicants' attention is drawn to MPEP 804 where it is disclosed that "the specification can always be used as a dictionary to learn the meaning of a term in a patent claim." *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in an application defines an obvious variation of an invention claimed in the patent (underlining added by examiner for emphasis). *In re Vogel*, 422 F.2d 438,164 USPQ 619,622 (CCPA 1970).

Consistent with the above underlined portion of the MPEP citation, attention is drawn to where US '580 discloses tabs on the graft that extend longitudinally beyond the opening of the graft (Figure 11). Although US '580 does not specifically disclose the tabs as folded over to attach to the attaching structures, US '791 teaches that a folding of tabs to secure two members is well known in the art (see Figures 1 and 2 of US '791). These tabs provide a secure attachment even when a pulling force is applied from below. Therefore, it would have been obvious at the time of the invention for the graft of US '580 to comprise tabs that are folded over to form a secure attachment, even in the presence of a pulling force from the graft.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 9, 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88 are rejected under 35 U.S.C. 103(a) as being obvious over Chuter et al. (US 6,652,580 B1) in view of Hickok (US 2,030,791).

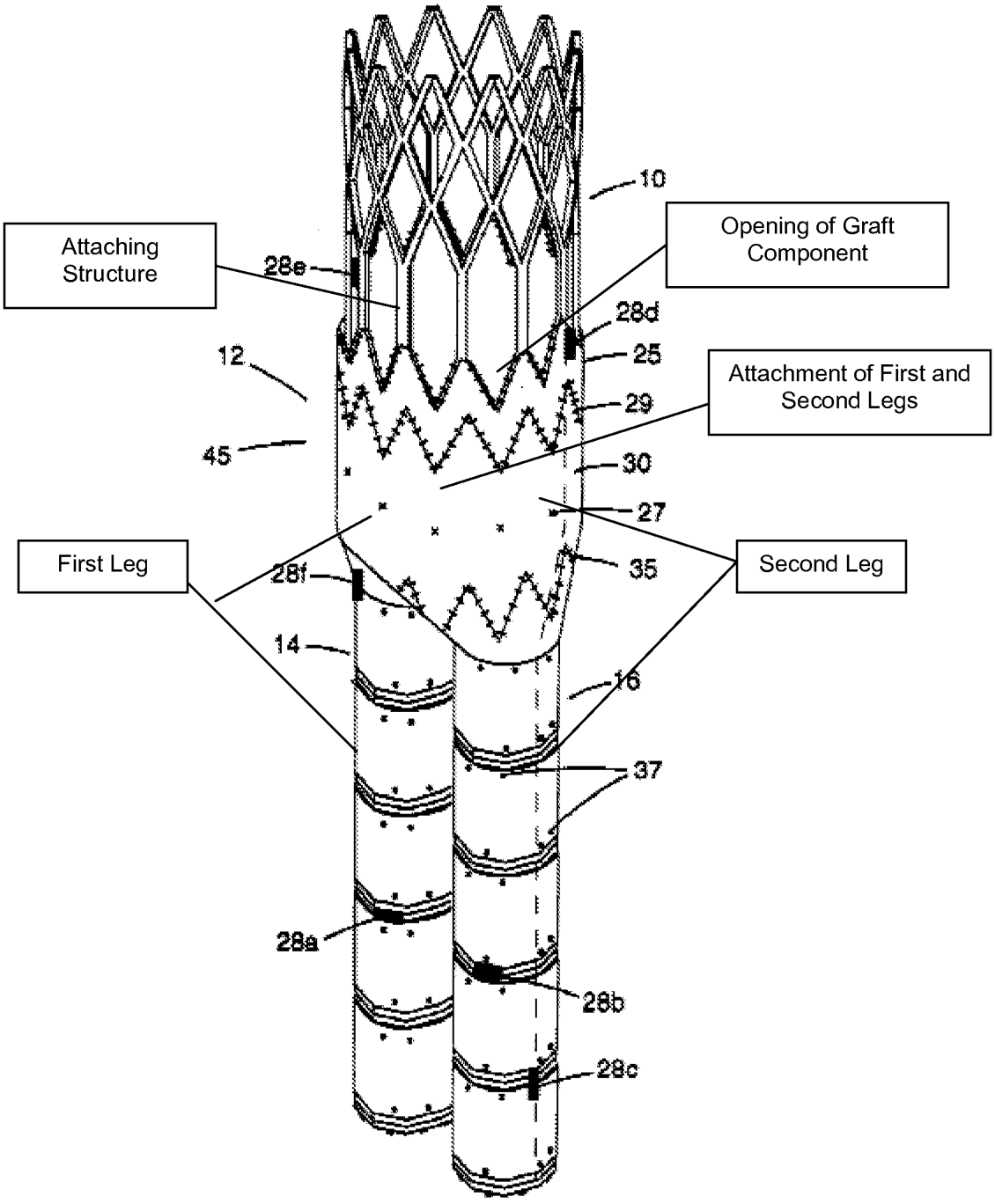
The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

For an explanation of the rejection see paragraph 3 above.

6. Claims 9, 11, 12, 15, 29-46, 48, 49, 56, 62, 70, 87, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. (US 6,280,466 B1) in view of Chobotov et al. (US 7,090,693 B1) in view of Hickok (US 2,030,791).

With regard to claims 9 and 31, as shown in Figure 3B, Kugler et al. (hereinafter Kugler) discloses an endovascular graft for treating vasculature (see entire document). The endovascular graft comprises graft component (45) having first and second leg portions (14 and 16) (Figure 3B). As shown below, the first and second legs area attached along a portion of their length and the graft component comprises an opening. Furthermore, the endovascular graft comprises an expandable frame (10) (column 7, lines 10-16). As shown in Figure 3B, the expandable frame (10) is longitudinally separated from the graft component (45) by attaching structures (shown below). Barbs (58) placed at the distal end (cranial end) of the expandable frame to a patient's lumen wall and therefore overlap the instantly claimed anchoring structure (Figure 6A; column 11, lines 28-63).

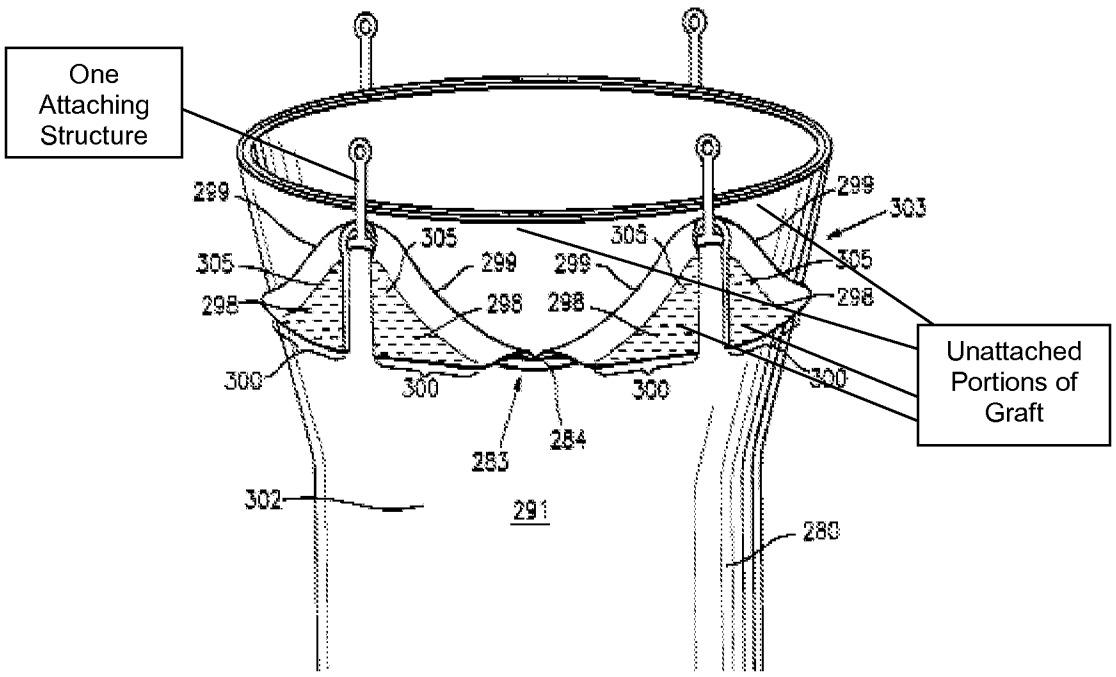


Kugler teaches the expandable frame is attached to the graft component by attaching structures (see above). These structures are sewn onto the graft for attachment (column 7, lines 10-16). Therefore, Kugler does not teach the attaching

structures are secured onto the graft by structures extending longitudinally from the graft that are then folded over the attaching structures to form a tab.

Chobotov et al. (hereinafter Chobotov) also discloses a graft (291) attached to attaching structures (285) (Figure 28). These attaching structures are then attached to a stent, similar to the endovascular graft of Kugler (column 16, lines 10-24 of Chobotov). As shown in Figure 29, flaps of the graft material are folded back over themselves and over the attaching structures to form tabs (column 18, line 65 through column 19, line 31). The tabs are then secured to the graft so that the attaching structures are maintained in place (column 19, lines 25-27; Figure 29).

As shown in Figure 29 and below, less than an entirety of the graft circumference is affixed to the attaching structure. The claims recite only one attaching structure. Therefore, each attaching structure only engages the graft at a select amount of points. However, even all the attaching structures, when taken together are not affixed to the entire graft circumference. As shown, below, free and unattached portions of the graft are present on the top layer and on the bottom layers.



However, Chobotov does not specifically disclose the folded tabs as initially extending longitudinally beyond the graft opening.

Hickok teaches that a folding of tabs to secure two members is well known in the art (see Figures 1 and 2). These tabs provide a secure attachment even when a pulling force is applied from below. As shown in Figure 1, the tabs initially extended longitudinally beyond the point of attachment and were then folded back on themselves. This is advantageous by allowing more material to fold over the tab and therefore provide a more secure attachment. Therefore, it would have been obvious at the time of the invention for the tabs of Kugler in view of Chobotov to initially extend beyond the graft opening. Then, when the tabs are folded over, more material is provided to allow a more secure attachment.

With regard to claim 11, the tabs as disclosed by Chobotov are part of the graft component (Figure 29).

With regard to claim 12, as shown in Figure 28 of Chobotov, tabs are formed by cutting the graft material.

With regard to claim 15, Chobotov teaches the tabs are secured to the under laying graft material through well known methods (column 19, lines 25-27). Since sutures are well known in the art to attach two components and Kugler specifically discloses them for attaching the graft to the expandable frame, it would have been obvious at the time of the invention to use sutures to secure the tabs.

With regard to claim 29, as shown in Figure 3B of Kugler, the graft component is bifurcated.

With regard to claim 30, Kugler teaches the expandable frame is comprised of a shape memory alloy which encompasses self-expanding.

With regard to claims 32 and 33, as shown in Figure 6A, the hooks or barbs (58) are curved or tapered.

With regard to claims 34 and 35, although Kugler does not specifically disclose the hooks or barbs as bidirectional or comprising a tail, the instant disclosure describes these parameters as merely preferable and does not describe them as contributing any unexpected result to the endovascular graft. As such these parameters are deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

With regard to claims 36 and 37, the barbs placed at the distal end or proximal end of the expandable frame would be located near a junction of stent struts and cut at the edge of the stent strut.

With regard to claims 38-40, 42, and 88, Kugler further discloses the graft component comprising reinforcing structures (16, 40) (Figure 5). These structures are further disclosed as stents (column 8, lines 6-22). As shown in Figure 5, the stents are on the interior of the graft.

With regard to claims 41 and 87, although Kugler does not also disclose reinforcing stent structures located along the interior of the graft, such is well known in the art and furthermore, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the endovascular. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

With regard to claims 43-46, 48, and 49, although Kugler does not disclose the reinforcing stent structures as also comprising a hook or barb, such would have been obvious at the time of the invention. Kugler discloses barbs on the expandable frame for attachment to a patient's vessel and additional barbs on the reinforcing stents would provide more support.

With regard to claims 56 and 70, as shown in Figure 3B, Kugler discloses a plurality of radiopaque markers (28a-c).

With regard to claim 62, as shown in Figure 6A of Kugler, the expandable frame comprises endpoints that are thicker than the struts.

Response to Arguments

7. Applicant's arguments filed 04/09/2009 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that the Hickok reference (US 2,030,791) is non-analogous art since one skilled in the art of implantable stent-grafts would not look to external clothing devices.

With respect to argument (A), although one skilled in the art of implantable stent-grafts may not look toward external clothing devices, one skilled in the art of implantable stent-grafts would look toward well known attachment means. Folding tabs over around a hook to form a secure attachment is well known as evidenced by Hickok. Additionally, Chobotov (as described above) discloses a tab folded over to form a secure attachment between a stent and a graft. Therefore, Chobotov, a stent-graft device, also shows that folding tabs over to form an attachment is well known, even in the stent-graft art. Additionally, Hickok discloses a well known apparatus that with a well known attachment means that most people, even those in the stent-graft art, are familiar with. One skilled in the art of implantable stent-grafts may look toward Hickok since the apparatus is so well known.

It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the

applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, since Hickok teaches a well known and secure attachment means, the teachings of Hickok are pertinent to the particular problem applicant was concerned with.

Specifically, applicant argues (B) that the office action mailed 02/25/2009 indicates that the tabs of Hickok serve "to provide a secure attachment even when a pulling force is applied from below," which is not supported by the Hickok reference.

With respect to argument (B), this advantage is inherent to the attachment means of Hickok. Although it is not specifically disclosed, it is an inherent property, absent evidence to the contrary.

Specifically, applicant argues © that the combination of Chuter et al. (US 6,652,580 B1) and Hickok (US 2,030,791) does not meet the claim limitations since Figure 11 of Chuter fails to disclose an attaching structure securing the expandable frame to the graft. Although Figure 10 depicts ties that secure the stent to the graft, the ties in Figure 11 pass through the holes in a perpendicular direction.

With respect to argument ©, since the ties enter through the holes, they secure the stent to the graft. Since the stent, shown in Figure 11, is maintained attached to the graft, the two components are therefore secured together. Additionally, Hickok provides a well known attachment that would also secure the stent to the graft, in place of the

Chuter attachment means. Since it replaces the Chuter attachment means, the combination of Chuter and Hickok is proper.

Specifically, applicant argues (D) that ring member (284) of Chobotov et al. (US 7,090,693) completely surrounds the opening of the circumference of the graft body (280). Therefore, Chobotov fails to disclose an attaching member wherein less than an entirety of a graft circumference is affixed to the attaching structure.

With respect to argument (D), as shown above, Chobotov teaches multiple layers of graft but only teaches one layer as folded over to form a tab attaching member. Therefore, the other layers of graft are not attached to the attaching structure. Furthermore, the claims recite an "opening of the graft component" as lacking other structure support. The opening of the graft component is not located where ring member (284) is located in Figure 28, but instead is distal of this location. The graft opening is the very distal end of the bottom layers of graft material.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

06/11/2009
/Amy T Lang/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/12/09